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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,446	01/18/2000	HUGH W. PRICE	7841-89	5954

1059 7590 05/03/2004

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EXAMINER	
HINES, JANA A	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/402,446	PRICE ET AL.15	
	Examiner	Art Unit	
	Ja-Na Hines	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-29,31-39 and 57-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-29, 31-39 and 57-73* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Amendment Entry

1. The amendment filed March 1, 2004 has been entered. Claims 37 and 39 have been amended. Claims 1-22, 30 and 40-56 have been canceled. Therefore, claims 23-29, 31-39 and 57-73 are under consideration in this Office Action.

Withdrawal of Rejections

2. The following objections and rejections have been withdrawn in view of applicants' amendments and arguments:

a) the objection of claims 57-73 under 37 CFR 1.75(c); and
b) the new matter rejection of claims 57-73 under 35 U.S.C. 112, first paragraph,

Allowable Subject Matter

3. The indication of allowability of claims is withdrawn in view of the new grounds of rejection. Rejections are based on the new grounds of rejection follow.

New Grounds of Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 23-29, 31-39 and 57-73 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 23 and 57 are drawn to a method of increasing the serum half-life of an immune globulin comprising combining the immune globulin and non-ionic surface active agent into an immune globulin preparation wherein the concentration of the immune globulin is about 2 weight percent to about 10 weight percent of the preparation and wherein said non-ionic surface active agent is in a concentration sufficient to increase the serum half-life of the immune globulin and parenterally administering to an animal in need thereof an immune globulin preparation and to a method of increasing the serum half-life of a polyclonal immune globulin comprising combining the immune globulin and non-ionic surface active agent into an immune globulin preparation wherein said non-ionic surface active agent is in a concentration sufficient to increase the serum half-life of the immune globulin and parenterally administering to an animal in need thereof an immune globulin preparation.

The written description in this case only specifically sets forth the anti-Rh_oD immune globulin, therefore the written description is not commensurate in scope with the claims drawn to every immune globulin and every polyclonal immune globulin. Neither the specification nor the claims teach that a variety of immune globulins or polyclonal immune globulins can be used in the method to increase serum half-lives. Neither the claims nor the specification teach how to ~~criteria as to~~ determine which immune

globulins or polyclonal immune globulins can be used in the claimed method to increase the serum half-life. There is no guidance as to what immune globulins can or cannot be used in the method being claimed. The specification does not include any other structural examples of immune globulins or polyclonal immune globulins useable in the claimed method.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117). The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*See Vas-Cath* at page 1116).

Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision (see page 115).

With the exception of specifically named anti-Rh_oD immune globulins, the skilled artisan cannot envision the detailed structure of the other immune globulins, thus conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. An adequate description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. Furthermore, *In The Reagents of the University of California v. Eli Lilly* (43 USPQ2d 1398-1412), the court held that a generic statement which defines a genus of by only their functional activity does not provide an adequate description of the genus. The court indicated that while Applicants are not required to disclose every species encompassed by a genus, the description of a genus is achieved by the recitation of a representative number of molecules falling within the scope of the claimed genus. Therefore only the recited anti-Rh_oD immune globulins and not the full

breadth of the claims meet the written description provision of 35 USC 112, first paragraph.

5. Claims 23-29, 31-39 and 57-73 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of increasing the serum half-life of an anti-Rh_oD immune globulin comprising combining the anti-Rh_oD immune globulin and non-ionic surface active agent into an immune globulin preparation wherein the concentration of the anti-Rh_oD immune globulin is about 2 weight percent to about 10 weight percent of the preparation and wherein said non-ionic surface active agent is in a concentration sufficient to increase the serum half-life of the anti-Rh_oD immune globulin and parenterally administering to an animal in need thereof the immune globulin preparation, does not reasonably provide enablement for a method of increasing the serum half-life of an immune globulin comprising combining the immune globulin and non-ionic surface active agent into an immune globulin preparation wherein the concentration of the immune globulin is about 2 weight percent to about 10 weight percent of the preparation and wherein said non-ionic surface active agent is in a concentration sufficient to increase the serum half-life of the immune globulin and parenterally administering to an animal in need thereof an immune globulin preparation or for a method of increasing the serum half-life of a polyclonal immune globulin comprising combining the immune globulin and non-ionic surface active agent into an immune globulin preparation wherein said non-ionic surface active agent is in a concentration sufficient to increase the serum half-life of the immune globulin and

parenterally administering to an animal in need thereof an immune globulin preparation. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The specification, beginning at page 16 teaches the preparation of Rh antibodies. The specification clearly discloses method steps, for preparing anti-Rh_oD immune globulin with preferred non-ionic surface-active agents. The steps have been set forth at pages 16-17 and 19-20 in the instant specification comprising the steps of using anti-Rh_oD immune globulin. It is noted that term immune globulin and polyclonal immune globulin at pages 15 and 17 of the instant specification merely define the terms of art. This rejection is not directed to the broad definitions of immune globulin or polyclonal immune globulin, but rather at the lack of teaching of a method for increasing serum half-live of each and every immune globulin and polyclonal immune globulins. The specification fails to teach a method for increasing serum half-life regarding the use of any other kind of immune globulin or polyclonal immune globulin besides anti-Rh_oD immune globulin. Furthermore, the specification fails to provide support for the combination of non-ionic surface-active agents with any other form of immune globulin or polyclonal immune globulin to create a method that increases serum half-life. There is no teaching of the claimed method or method steps that increase serum half-life using a variety of immune globulin and non-ionic surface-active agents.

All the examples are drawn to anti-Rh_oD immune globulin. Thus applicants' clearly show that undue experimentation would be required to determine all the other

types of immune globulin which could be used in the method of increasing the serum half-life of an anti-Rh_oD immune globulin comprising combining the anti-Rh_oD immune globulin and non-ionic surface active agent into an immune globulin preparation and wherein said non-ionic surface active agent is in a concentration sufficient to increase the serum half-life of the anti-Rh_oD immune globulin and parenterally administering to an animal in need thereof the immune globulin preparation. There is no teaching in the specification of using other types of immune globulin. There is no disclosure that other immune globulin react substantially the same as anti-Rh_oD immune globulin with respect to increasing their serum half-life when combined with a non-ionic surface-active agent.

The teaching within the specification is limited to the steps and anti-Rh_oD immune globulin recited in the instant specification. The specification fails to teach examples of any other ~~the~~ combination of ~~other~~ immune globulins, such that without the exact and precise method steps and specific reagents the immune globulin preparations and methods cannot be produced. The broad method claims do not require the precise reagents disclosed in the instant specification as useable in the claimed method thus, one of ordinary skill in the art would be required to determine the appropriate immune globulins, additional reagents and conditions required to increase the serum half-life of an immune globulin comprising combining any immune globulin and any non-ionic surface active agent into an immune globulin preparation.

Therefore, the specification fails to enable a method of increasing the serum half-life of an immune globulin comprising combining ~~the~~ any immune globulin and non-ionic

surface active agent into an immune globulin preparation wherein the concentration of the immune globulin is about 2 weight percent to about 10 weight percent of the preparation and wherein said non-ionic surface active agent is in a concentration sufficient to increase the serum half-life of the immune globulin and parenterally administering to an animal in need thereof an immune globulin preparation or for a method of increasing the serum half-life of a polyclonal immune globulin comprising combining the immune globulin and non-ionic surface active agent into an immune globulin preparation wherein said non-ionic surface active agent is in a concentration sufficient to increase the serum half-life of the immune globulin and parenterally administering to an animal in need thereof an immune globulin preparation. Without information of the specific immune globulin, one of skill in the art could not predict which immune globulins would result in the desired method of increasing serum half-life, thereby requiring undue experimentation.

The method of increasing the serum half-life of an immune globulin or polyclonal immune globulin under the claimed method steps would not predictably result in a method of increasing the serum half-life. The specification only teaches the use of anti-Rh_oD immune globulin, specific reagents, conditions and steps that may result in increased serum half-life. The specification does not provide guidance on how any immune globulin's serum half-life can be increased under the recited conditions. No working examples are shown containing a method for increasing serum half-life of a variety of immune globulins comprising the recited steps. Without such information, one of skill in the art could not predict which method steps would result in the desired

increased serum half-life. Accordingly, one of skill in the art would be required to perform undue experimentation to use any immune globulin in a method of increasing the serum half-life of an immune globulin comprising a combination step and administration step. Therefore, one skilled in the art could not make and/or use the invention without undue experimentation.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 71 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 71 is unclear as to how one can administer a lyophilized preparation of immune globulin to an animal. It is also unclear if the preparation must be re-constituted first, or if applicant intends another form of administration. Therefore, clarification is required to overcome the rejection.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is 571-272-0859. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 571-272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Ja-Na Hines
April 26, 2004

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